

EPA REGISTRATION FILE 87427-19



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

87427-19

Date of Issuance:

1/5/17

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Imazethapyr Tech

Name and Address of Registrant (include ZIP Code):

Ann M. Tillman
Agent for AXSS Technical Holdings, LLC
AXSS Technical Holdings, LLC
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Erik Kraft, Acting Product Manager 24
Fungicide & Herbicide Branch, Registration Division (7505P)

Date:

1/5/17

2. Be aware that proposed data requirements have been identified in a Work Plan. For more information on these proposed data requirements, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:
<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>
3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 87427-19."
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 10/28/2016

If you have any questions, please contact Lisa Pahel by phone at (703) 347-0459, or via email at pahel.lisa@epa.gov.

Enclosure: Product Chemistry Review dated 12/13/2016, DP#432436; Similarity Clinic Memo dated 03/15/2016, DP#432245

Imazethapyr Tech

FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT

Imazethapyr: (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl-3-pyridinecarboxylic acid

OTHER INGREDIENTS:

TOTAL

% BY WT

98.4%

1.6%

100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION/PRECAUCION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

(If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
If on skin:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a poison control center or doctor immediately for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact CHEMTREC at 1-800-424-9300 for emergency medical information.	

EPA Reg. No. 87427-

EPA Est. No.

Manufactured For:

AXSS Technical Holdings, LLC
111 Martin Road
Fulton, MS 38843

NET CONTENTS: lbs. (kg)

ACCEPTED

01/05/2017

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 87427-19

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Avoid breathing dust. Wear protective eyewear. Wear long sleeved shirt and long pants, socks, shoes, and gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash before re-use.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only For Formulation into Herbicide Products Intended For:

1. **Terrestrial Food Crops:** alfalfa, clover, endive (FL only), field corn (CLEARFIELD corn hybrids only), Legume Vegetables (Crop Group 6), leaf and head lettuce (FL only), peanuts, CLEARFILED rice, and soybeans;
2. Uses for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration;
3. Uses for experimental purposes that are in compliance with U.S. EPA requirements for their formulated products.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal

PESTICIDE STORAGE: Store in original container only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, mop up and remove to chemical waste storage area until proper disposal can be made if product cannot be used according to label.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of federal law. If these wastes cannot be disposed of according to label instructions, contact your State Pesticide or Environmental Protection Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Fiber drums with liner: Nonrefillable container. Do not reuse or refill this container. Completely empty liner into application equipment by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then offer drum and liner for recycling if available. If not available, dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If burned stay out of smoke. If drum is contaminated and cannot be reused, dispose of in the same manner required for its liner.

Terms and Conditions of Use

If terms of the following Warranty Disclaimer, Inherent Risks of Use, and Limitation of Remedies are not acceptable, return unopened package at once to the seller for a full refund of purchase price paid. Otherwise, use by the buyer or any other user constitutes acceptance of the terms under Warranty Disclaimer, Inherent Risks of Use and Limitations of Remedies.

Warranty Disclaimer

AXSS Technical Holdings, LLC warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, AXSS TECHNICAL HOLDINGS, LLC MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

Inherent Risks of Use

It is impossible to eliminate all risks associated with use of this product. Unintended consequences may result because of such factors as use of the product contrary to label instructions, presence of other materials, or other factors, all of which are beyond the control of AXSS Technical Holdings, LLC or the seller. All such risks shall be assumed by buyer.

Limitation of Remedies

The exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to, at AXSS Technical Holdings, LLC election, one of the following: Refund of purchase price paid by buyer or user for product bought, or Replacement of amount of product used.

To the extent consistent with applicable law, AXSS Technical Holdings, LLC shall not be liable for losses or damages resulting from handling or use of this product unless AXSS Technical Holdings, LLC is promptly notified of such loss or damage in writing. In no case, to the extent consistent with applicable law, shall AXSS Technical Holdings, LLC be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of AXSS Technical Holdings, LLC or the seller is authorized to vary or exceed the terms of the Warranty Disclaimer or this Limitation of Remedies in any manner.

[EPA approval date]

Reg Number: 87427-RO Reg. Type: Product Registration - Section 3 Status: Under Review (07-Mar-2016)

Name: IMAZETHAPYR TECH

[<View Registration Details>](#)

(No New Receipts)

S:	Submission Type	OPP Rec'd Date	Resubmission	Description

...Decisions...

Data Requirements

D: Pending; 514742; 87427-RO; R334; NEW PRO

75-Day Letters

S: 982408; 3/7/2016; New Registration; 835

S: 982408 Reg #: 87427-RO

Submission Type: New Registration

Resubmission?: ☒ Yes ☒ No

E-Sub #: 10367

Decision #: 514742; R334; NEW PRODUCT; MUP OR END USE PRODUCT V

Submitter Company: TACOMA AG, LLC

Application Date: 07-Mar-2016

OPP Received Date: 07-Mar-2016 Date Sent to Risk manager: 08-Mar-2016

Studies Included?: ☒ Yes ☐ NoFast Track?: ☒ Yes ☐ NoForm A Signed?: ☐ Yes ☐ No ☒ None

Date:

Form B Signed?: ☒ Yes ☐ No ☒ None

Date:

Reviewer: Pahel, Lisa

Received DT:

Editable Due DT:

Submission Due DT: 28-Feb-2017 Response: 0, 07-Mar-2016

Priority Weight:

Priority Points:

Comments: Application for registration of Tacoma Ag Imazethapyr Tech
(3/22/16 et)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 09, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PYSIS REGULATORY CONSULTING INC
TACOMA AG, LLC
4110 136TH ST, CT NW
GIG HARBOR, WA 98332

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 07-MAR-16. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Pahel, Lisa

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Thursday, January 05, 2017 7:17 AM
To: Pahel, Lisa
Subject: RE: Pending registration 87427-RO
Attachments: 20170105 Imazethapyr 8570-1 App updt.pdf; 87427-RO 20170103 8570-35 Public_updated.pdf; 87427-RO 20170103 8570-35 Agency_updated.pdf; 87427-RO 20170103 8570-34.pdf; 87427-RO 20161028 8570-4 updt.pdf; 087427-xx 20170105 Imazethapyr Tech Label.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Lisa,

Attached, please find the updated forms to reflect the transfer of this pending registration from Tacoma Ag to AXSS Technical Holdings. The files include:

- updated 8570-1, Application
- updated 8570-4, CSF
- updated 8570-34, Certification with Respect to Citation of Data
- updated 8570-35, Agency Data Matrix
- updated 8570-35, Public version of the Data Matrix
- updated label for Imazethapyr Tech

Let me know if you need anything further.

Ann

From: Pahel, Lisa [mailto:Pahel.Lisa@epa.gov]
Sent: January 04, 2017 2:32 PM
To: Ann Tillman <Ann@PyxisRC.com>
Subject: RE: Pending registration 87427-RO

Hi Ann,

This pending registration was transferred from Tacoma Ag, LLC to AXSS Technical Holdings, Inc. I'm assuming you will want to change the name from "Tacoma Ag Imazethapyr Tech?" If so, you would need to submit a revised application, label, and other supporting documentation with the new product name and pending reg number. Please let me know if you have any questions.

Thanks,
Lisa

From: Pahel, Lisa
Sent: Tuesday, January 03, 2017 4:55 PM
To: 'Ann Tillman' <Ann@PyxisRC.com>
Subject: RE: Pending registration 87427-RO

Thank you, Ann. I'll be in touch if we need anything else.

Pahel, Lisa

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Tuesday, January 03, 2017 4:39 PM
To: Pahel, Lisa
Subject: RE: Pending registration 87427-RO
Attachments: 87427-RO 20170103 8570-35 Public.pdf; 87427-RO 20170103 8570-35 Agency.pdf; 87427-RO 20170103 8570-34.pdf

Lisa,

Copies of the updated data matrices--Agency and Public versions—are attached. I also updated the Certification, EPA form 8570-34.

Ann

From: Pahel, Lisa [mailto:Pahel.Lisa@epa.gov]
Sent: December 22, 2016 4:11 PM
To: Ann Tillman <Ann@PyxisRC.com>
Subject: RE: Pending registration 87427-RO

Hi Ann,

That's fine.

Best,
Lisa

From: Ann Tillman [mailto:Ann@PyxisRC.com]
Sent: Thursday, December 22, 2016 3:54 PM
To: Pahel, Lisa <Pahel.Lisa@epa.gov>
Subject: RE: Pending registration 87427-RO

Lisa,

Will it be okay to send the matrix the first week in Jan.?

Ann

From: Pahel, Lisa [mailto:Pahel.Lisa@epa.gov]
Sent: December 22, 2016 3:07 PM
To: Ann Tillman <Ann@PyxisRC.com>
Subject: RE: Pending registration 87427-RO

Hi Ann,

Just checking in on the status of the updated data matrix.

Thanks,
Lisa

From: Pahel, Lisa
Sent: Monday, November 14, 2016 8:59 AM
To: 'Ann Tillman' <Ann@PyxisRC.com>
Subject: RE: Pending registration 87427-RO

Great, thanks for the update Ann

From: Ann Tillman [mailto:Ann@PyxisRC.com]
Sent: Friday, November 11, 2016 11:59 AM
To: Pahel, Lisa <Pahel.Lisa@epa.gov>
Subject: RE: Pending registration 87427-RO

Hi, Lisa,

I wanted to give you an update on the revision to the data matrix to add those MRIDs. We are currently talking with BASF about these studies and will send an updated matrix after discussions are complete.

Ann

From: Pahel, Lisa [mailto:Pahel.Lisa@epa.gov]
Sent: November 02, 2016 10:33 AM
To: Ann Tillman <Ann@PyxisRC.com>
Subject: Pending registration 87427-RO

Hi Ann,

I'm reviewing the pending registration for 87427-RO. At your earliest convenience, please submit an updated data matrix to me or through the portal, adding the following MRIDs:

MRID 46254702
MRID 46254703
MRID 46123701

Please let me know if you have any questions.

Thanks,
Lisa

Lisa Pahel
Environmental Protection Specialist
Fungicide and Herbicide Branch
Registration Division
Office of Pesticide Programs
703-347-0459



PYXIS REGULATORY CONSULTING, INC.

4110 136th St. Ct. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

March 7, 2016

MRID 498415-00

ELECTRONIC DELIVERY

Heather Garvie (PM 24)
Document Processing Desk (**REGFEE**)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Tacoma Ag, LLC
Tacoma Ag Imazethapyr Tech (EPA File Symbol 83520-)
Application for New Pesticide Registration
PRIA Category R334

Dear Ms. Garvie,

On behalf of Tacoma Ag, LLC, we are submitting an application for registration of Tacoma Ag Imazethapyr Tech, a technical product containing the active ingredient imazethapyr. In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Certification with Respect to Citation of Data (EPA Form 8570-34)
4. Agency Internal Use Copy of the Data Matrix (EPA Form 8570-35)
5. Public File Copy of the Data Matrix (EPA Form 8570-35)
6. One (1) copy of the proposed label for Tacoma Ag Imazethapyr Tech
7. Copy of the PRIA payment
8. Letter of Authorization
9. Product Specific Data:

MRID	Guideline	Study Title
49841501	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Tacoma Ag Imazethapyr Tech. <i>Contains Confidential Business Information.</i>
49841502	830.1700, 830.1800	Xu, J. Five-Batch Analysis of Imazethapyr TGAI – Validation of Analytical Methodology for the Assay of Active Ingredient and Impurities in Imazethapyr TGAI and Subsequent 5-Batch Analysis of the Test Item. <i>Contains Confidential Business Information.</i>

MRID	Guideline	Study Title
49841503	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6317, 830.6320, 830.7000, 830.7050, 830.7200, 830.7300, 830.7370, 830.7550, 830.7840	Xu, J. Physical and Chemical Characterization of Imazethapyr TGAI-Color, Physical State, Odor, Stability, Corrosive Characteristic, Oxidation/Reduction, pH, UV/Vis Absorption, Density, Dissociation Constant, Melting Point, Partition Coefficient and Solubility.
49841504	830.6315, 830.6316, 830.6319, 830.7100, 830.7220, 830.7520, 830.7950	Tillman, A. M. Tacoma Ag Imazethapyr Tech Physical and Chemical Properties and Waiver Requests.

Tacoma Ag, LLC is using the selective method of data support. As per EPA's interpretations of 40 CFR Parts 152.90 - 152.96, Tacoma Ag, LLC submitted notices of intent to apply and offers to pay to the extent required by FIFRA § 3(c)(1)(F). This action falls under Category R334 (54: New MUP with unregistered source of active ingredient; selective data citation). The fee due which has been paid is \$19,838.

We trust you will find this application complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone at (253) 853-7369 if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures

cc: K. Howard, Tacoma Ag, LLC

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. Ct. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

March 3, 2016

VIA CERTIFIED MAIL, RETURN RECEIPT REQUESTED

7015 1520 0001 8117 4276

BASF Corporation
P. O. Box 13528
26 Davis Drive
Research Triangle Park, NC 27709

RE: Tacoma Ag Imazethapyr Tech: Offer to Pay

Dear Sir/Madam:

Tacoma Ag, LLC (Tacoma Ag) is applying for registration under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.*, for a technical product called Tacoma Ag Imazethapyr Tech (EPA Reg. No. 83520-), containing imazethapyr (Chemical Code 128922) as the active ingredient.

Tacoma Ag's application uses the straight selective method of data support (40 C.F.R. §§ 152.90 – 152.96)¹. Tacoma Ag hereby provides its notice of intent to apply for this registration and offers to pay compensation to BASF Corporation (BASF) to the extent required by FIFRA § 3(c)(1)(F), for the following data, provided that BASF is identified by EPA as the "original data submitter" for such data.

GDL No.	GDL Title	MRID No.
835.7100	Ground Water Monitoring	46123702
860.1340	Residue Analytical Methods	46254704
860.1380	Storage Stability	45528001
860.1400	Magnitude of the Residue in Fish	45607101
		46254701

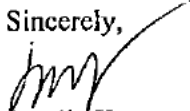
Further, Tacoma Ag hereby offers to commence negotiations to determine the amount and terms of compensation, if any, due for these studies.

Please note that, in accordance with 40 C.F.R. § 152.93(b)(3), Tacoma Ag is not offering to pay for studies cited in Tacoma Ag's application that were originally submitted to the EPA more than 15 years before the date of Tacoma Ag's application for the above-mentioned product. However, as set forth in FIFRA § 3(c)(1)(F) and as affirmed by EPA, only data originally submitted within 15 years of EPA's approval of Tacoma Ag's application are eligible for compensation.

If you are aware that any studies listed above do not satisfy applicable data requirements, please advise us within the next 60 days. Please also advise us whether you have submitted a replacement study to satisfy the applicable data requirement and, if so, the guideline number, study title, and MRID number of each such replacement study. We reserve the right to revise this offer to pay upon receiving this information from you.

Please contact me by phone at (253) 853-7369 or by email at Janelle@PyxisRC.com if you have any questions. Thank you very much for your cooperation.

Sincerely,


Janelle Kay
Agent for Tacoma Ag, LLC
cc: Tacoma Ag, LLC

¹ Tacoma Ag is not using the cite-all option under the selective method for any data requirement.



We create chemistry

October 28, 2016

U.S. Environmental Protection Agency
Office of Pesticide Programs (7505P)
Document Processing Desk, 7504P
Room S-4900
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 2202

Attention: Mr. Erik Kraft, Registration Division, PM Team 24 (Acting)

SUBJECT: Tacoma Ag Application for Imazethapyr Technical Registration
EPA Admin. No. 83520-39

Reference: Active Ingredient: Imazethapyr
Pursuit® herbicide Technical, EPA Reg. No. 241-309

Mr. Kraft:

BASF Corporation (BASF, Company Number 7969) received an Offer to Pay Letter from Tacoma Ag (Company Number 83520) for studies cited in its petition for registration of Imazethapyr Technical. A copy of this letter is included with this correspondence. BASF finds the study list in the Offer to Pay Letter to be deficient, as the following relevant studies are not cited:

MRID 46254702

Seiferlein, M. (2004). A Meat and Milk Magnitude of the Residue Study with CL 288511 (Reg. No. 4110971; a Metabolite of BAS 685 H, Imazethapyr) in Lactating Dairy Cows. Final Report. Guideline Number **860.1400**.

MRID 46254703

Seiferlein, M. (2004). Validation of BASF Analytical Method M3512 Entitled 'BAS 685 H (Imazethapyr): LC/MS Determination and LC/MS/MS Confirmatory Method for BAS 685 H And CL 288511 (Metabolite of BAS 685 H) in Crawfish' in Matrices of Animal Origin'. Final Report. Guideline Number **860.1340**.

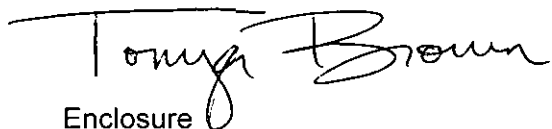
MRID 46123701

Jackson, S. (2003). A Small-Scale Prospective Ground-Water Monitoring Study for Imazethapyr on Corn in the Southeastern (Georgia) United States. Guideline Number **835.7100**.

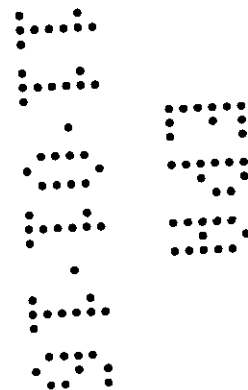
BASF appreciates EPA's attention and thorough evaluation of this matter. Further, BASF acknowledges the importance of complete study citation during the pesticide registration process. If you have any questions, need clarification or more information, please feel free to contact me by phone at (919) 547 – 2942 or by e-mail at tonya.brown@basf.com.

Sincerely,

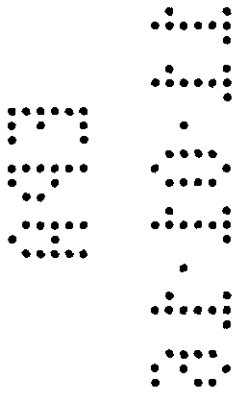
Tonya Brown
Regulatory Affairs
BASF Corporation



Enclosure



Pursuit® is a Registered Trademark of BASF





United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 87427-	2. EPA Product Manager V. Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) AXSS Technical Holdings, LLC/Imazethapyr Tech	PM# 1	
5. Name and Address of Applicant (Include ZIP Code) AXSS Technical Holdings, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136th St. Ct. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 241-309 Product Name Pursuit Herbicide Technical	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under PRIA Category R334 (53: New product; selective data citation). The fee for this action is \$19,838 and has been paid.

Section - III

1. Material This Product Will Be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55.12 lbs. (25 kg)		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Ann M. Tillman		Title Agent	
		Telephone No. (Include Area Code) (253) 853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name Ann M. Tillman		5. Date Jan. 5, 2016	



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WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number c/o Pyxis Regulatory Consulting 4110 136th St. Ct. NW Gig Harbor, WA 98332 (253) 853-7369	EPA Registration Number/File Symbol 87427-RO
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Active Inredient(s) and/or representative test compound(s)
Imazethapyr

Date
Jan. 3, 2017

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
TGA1

Product Name
Imazethapyr Tech

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Digitally signed by Ann M. Tillman
 DN: cn=Ann M. Tillman, o=Pyxis
 Regulatory Consulting, Inc., ou=Pyxis,
 email=Ann@PyxisRC.com, c=US
 Date: 2017.01.03 15:12:37 -0500

Date

Jan. 3, 2017

Typed or Printed Name and Title

Ann M. Tillman, Agent

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DATA MATRIX

Date Jan. 3, 2017	EPA Reg No./File Symbol 87427-RO	Page 1 of 18
Applicant's/Registrant's Name & Address AXSS Technical Holdings, LLC 111 Martin Road Fulton, MS 38843	Product Imazethapyr Tech	

Ingredient Imazethapyr (CAS No. 81335-77-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data					
830.1550	Product Identity and Composition	49841501	Tacoma Ag, LLC	OWN	
830.1600	Description of Materials Used to Produce the Product	49841501	Tacoma Ag, LLC	OWN	
830.1620	Description of Production Process	49841501	Tacoma Ag, LLC	OWN	
830.1650	Description of Formulation Process				Not required ¹
830.1670	Discussion of Formation of Impurities	49841501	Tacoma Ag, LLC	OWN	
830.1700	Preliminary Analysis	49841502	Tacoma Ag, LLC Tacoma Ag, LLC	OWN OWN	
830.1750	Certified Limits	49841501	Tacoma Ag, LLC	OWN	
830.1800	Enforcement Analytical Method	49841502 49841501	Tacoma Ag, LLC Tacoma Ag, LLC	OWN OWN	
830.6302	Color	49841503	Tacoma Ag, LLC	OWN	
830.6303	Physical State	49841503	Tacoma Ag, LLC	OWN	
830.6304	Odor	49841503	Tacoma Ag, LLC	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	49841503	Tacoma Ag, LLC	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility	49841503	Tacoma Ag, LLC	OWN	
830.6315	Flammability	49841504	Tacoma Ag, LLC	OWN	Waiver ²
830.6316	Explosibility	49841504	Tacoma Ag, LLC	OWN	Waiver ³
830.6317	Storage Stability	49841503	Tacoma Ag, LLC	OWN	
830.6319	Miscibility	49841504	Tacoma Ag, LLC	OWN	Not required ⁴

Signature 	Name and Title Ann M. Tillman, Agent	Date Jan. 3, 2017
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Applicant's/Registrant's Name & Address AXSS Technical Holdings, LLC 111 Martin Road Fulton, MS 38843	Product Imazethapyr Tech	

Ingredient Imazethapyr (CAS No. 81335-77-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6320	Corrosion Characteristics	49841503	Tacoma Ag, LLC	OWN	
830.6321	Dielectric Breakdown Voltage				Not required ⁵
830.7000	pH	49841503	Tacoma Ag, LLC	OWN	
830.7050	UV/Visible Absorption	49841503	Tacoma Ag, LLC	OWN	
830.7100	Viscosity	49841504	Tacoma Ag, LLC	OWN	Not required ⁶
830.7200	Melting Point/Melting Range	49841503	Tacoma Ag, LLC	OWN	
830.7220	Boiling Point/Boiling Range	49841504	Tacoma Ag, LLC	OWN	Not required ⁷
830.7300	Density/Relative Density/Bulk Density	49841503	Tacoma Ag, LLC	OWN	
830.7370	Dissociation Constants in Water	49841503	Tacoma Ag, LLC	OWN	
830.7520	Particle size, fiber length, diameter distribution	49841504	Tacoma Ag, LLC	OWN	Waiver ⁸
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	49841503	Tacoma Ag, LLC	OWN	
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	49841503	Tacoma Ag, LLC	OWN	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	49841504	Tacoma Ag, LLC	OWN/PL	

Signature



Name and Title

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Applicant's/Registrant's Name & Address

AXSS Technical Holdings, LLC
111 Martin Road
Fulton, MS 38843

Product

Imazethapyr Tech

Ingredient Imazethapyr (CAS No. 81335-77-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral Toxicity: Rat	00159375		OLD	See endnote ⁹
870.1200	Acute Dermal Toxicity: Rat	00159375		OLD	See endnote ¹⁰
870.1300	Acute Inhalation Toxicity: Rat	00159378		OLD	See endnote ¹¹
870.2400	Primary Eye Irritation: Rabbit	00159375		OLD	See endnote ¹²
870.2500	Primary Dermal Irritation	00159375		OLD	See endnote ¹³
870.2600	Dermal Sensitization	00159379		OLD	See endnote ¹⁴
Generic Data					
850.2100	Acute Avian Oral Toxicity	00159722 00159723		OLD OLD	See endnote/ Not required ¹⁵
850.2200	Acute Avian Dietary Toxicity	00159724 00159725		OLD OLD	See endnote ¹⁶
850.2400	Wild Mammal Toxicity				Not required
850.2300	Avian Reproductive Toxicity	45161303 45161304		OLD OLD	See endnote ¹⁷
850.2500	Simulated or Actual Field Testing				Not required
850.1075	Freshwater Fish Toxicity	00159726 00159727 00159728 45161305 45161306		OLD OLD OLD OLD OLD	See endnote ¹⁸

Signature



Name and Title

Ann M. Tillman, Agent

Date

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Applicant's/Registrant's Name & Address

AXSS Technical Holdings, LLC
111 Martin Road
Fulton, MS 38843

Product

Imazethapyr Tech

Ingredient Imazethapyr (CAS No. 81335-77-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1010	Freshwater Invertebrate Toxicity	00159729 45161307 45161309 45205801 45161308		OLD OLD OLD OLD OLD	See endnote ¹⁹
850.1025, 850.1035, 850.1045, 850.1055, 850.1075	Acute Toxicity Estuarine and Marine Organisms	45161310 45161311 45161312		OLD OLD OLD	See endnote ²⁰
850.1300	Aquatic Invertebrate Life Cycle (Freshwater)	45161314		OLD	See endnote ²¹
850.1350	Aquatic Invertebrate Life Cycle (Saltwater)				Not required ²²
850.1400	Fish Early Life Stage (Freshwater)	45161313		OLD	See endnote ²³
850.1400	Fish Early Life Stage (Saltwater)				Not required ²⁴
850.1500	Life Cycle Fish				Not required
850.1710, 850.1730, 850.1850	Aquatic Organisms Bioavailability, Biomagnification, Toxicity	40429413		OLD	See endnote ²⁵
850.1950	Simulated or Actual Field Testing for Aquatic Organisms				Not required
850.1735	Whole Sediment: Acute Freshwater Invertebrates				Not required ²⁶
850.1740	Whole Sediment: Acute Marine Invertebrates				Not required ²⁷
850.3020	Honey Bee Acute Contact Toxicity	00159729		OLD	See endnote ²⁸
N/A	Honey Bee Acute Oral Toxicity				Reserved ²⁹

Signature



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DATA MATRIX

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Ingredient Imazethapyr (CAS No. 81335- 77-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Honey Bee Larval Acute Oral Toxicity				Reserved ³⁰
N/A	Honey Bee Larval Chronic Oral Toxicity				Reserved ³¹
850.3030	Honeybee Toxicity of Residues on Foliage				Waived ³²
850.3040	Field Testing for Pollinators				Not required
870.6100	Delayed Neurotoxicity (Acute) – Hen				Not required
870.6200	Acute Neurotoxicity – Rat				Not required ³³
870.3100	90-Day Oral: Rodent	00159381		OLD	See endnote ³⁴
870.3150	90-Day Oral: Non-Rodent	00159382		OLD	See endnote ³⁵
870.3200	21/28-Day Dermal Toxicity	00159383		OLD	See endnote ³⁶
870.3250	90-Day Dermal Toxicity				Not required
870.3465	90-Day Inhalation Toxicity				Not required ³⁷
870.6100	28-Day Delayed Neurotoxicity Hen				Not required
870.6200	90-Day Neurotoxicity				Not required ³⁸
870.4100	Chronic Oral Rodent	40429414		OLD	See endnote ³⁹
870.4200	Carcinogenicity	40429414 40429415		OLD OLD	See endnote ⁴⁰
870.3700	Reproduction/Developmental Toxicity Screening Test	40429417 00159384		OLD OLD	See endnote ⁴¹
870.3800	2-Generation Reproduction: Rat	40429418		OLD	See endnote ⁴²
870.6300	Developmental Neurotoxicity Study				Not required
870.5100	Bacterial Reverse Mutation Test	00159719		OLD	See endnote ⁴³

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Applicant's/Registrant's Name & Address AXSS Technical Holdings, LLC 111 Martin Road Fulton, MS 38843	Product Imazethapyr Tech	

Ingredient Imazethapyr (CAS No. 81335-77-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5300, 830.5375	<i>In vitro</i> Mammalian Cell Assay	40429419 40438201		OLD OLD	See endnote ⁴⁴
870.5385, 870.5395, 870.5450, 870.5550	<i>In vivo</i> Cytogenetics and Other Effects	00159720 00159721		OLD OLD	See endnote ⁴⁵
870.7485	Metabolism and Pharmacokinetics	40429420 41467703		OLD OLD	See endnote ⁴⁶
870.7200	Companion Animal Safety				Not required
870.7600	Dermal Penetration				Not required
870.7800	Immunotoxicity				Not required ⁴⁷
875.1100	Dermal Exposure – Outdoor		Agricultural Handler Exposure Task Force	OWN	See endnote ⁴⁸
875.1200	Dermal Exposure – Indoor				Not required
875.1300	Inhalation Exposure – Outdoor		Agricultural Handler Exposure Task Force	OWN	See endnote ⁴⁸
875.1400	Inhalation Exposure - Indoor				Not required
875.1500	Biological Monitoring		Agricultural Handler Exposure Task Force	OWN	See endnote ⁴⁸
875.1600	Data Reporting and Calculations		Agricultural Handler Exposure Task Force	OWN	See endnote ⁴⁸
875.1700	Product Use Information		Agricultural Handler Exposure Task Force	OWN	See endnote ⁴⁸

Signature 	Name and Title Ann M. Tillman, Agent	Date Jan. 3, 2017
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Applicant's/Registrant's Name & Address AXSS Technical Holdings, LLC 111 Martin Road Fulton, MS 38843			Product Imazethapyr Tech		
Ingredient Imazethapyr (CAS No. 81335-77-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues				Not required ⁴⁹
875.2200	Soil Residue Dissipation		Outdoor Residential Exposure Task Force Agricultural Re-Entry Exposure Task Force	OWN	See endnote ⁵⁰
875.2300	Indoor Surface Residue Dissipation				Not required
875.2400	Dermal Exposure		Outdoor Residential Exposure Task Force Agricultural Re-Entry Exposure Task Force	OWN	See endnote ⁵⁰
875.2500	Inhalation Exposure		Outdoor Residential Exposure Task Force Agricultural Re-Entry Exposure Task Force	OWN	See endnote ⁵⁰
875.2600	Biological Monitoring		Outdoor Residential Exposure Task Force Agricultural Re-Entry Exposure Task Force	OWN	See endnote ⁵⁰

Signature 	Name and Title Ann M. Tillman, Agent	Date Jan. 3, 2017
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Ingredient Imazethapyr (CAS No. 81335-77-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2700	Product Use Information		Outdoor Residential Exposure Task Force Agricultural Re-Entry Exposure Task Force	OWN	See endnote ⁵⁰
875.2800	Descriptions of Human Activity		Outdoor Residential Exposure Task Force Agricultural Re-Entry Exposure Task Force	OWN	See endnote ⁵⁰
875.2900	Data Reporting and Calculations		Outdoor Residential Exposure Task Force Agricultural Re-Entry Exposure Task Force	OWN	See endnote ⁵⁰
875.3000	Nondietary Ingestion Exposure				Not required
201-1	Droplet Size Spectrum		Spray Drift Task Force	OWN	See endnote ⁵¹
202-1	Droplet Size Spectrum		Spray Drift Task Force	OWN	See endnote ⁵¹
850.4100	Tier 1: Seedling Emergence	44996102		OLD	See endnote ⁵²
850.4150	Tier 1: Vegetative Vigor	44996101		OLD	See endnote ⁵³

Signature 	Name and Title Ann M. Tillman, Agent	Date Jan. 3, 2017
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Ingredient Imazethapyr (CAS No. 81335-77-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4400, 850.5400	Tier 1: Aquatic Plant Growth	41888101 45161318 45161319 45161321 45161323 45161324 45161325 45161326 45161327		OLD OLD OLD OLD OLD OLD OLD OLD OLD GAP	See endnote ⁵⁴
850.4100	Tier 2: Seedling Emergence	44996102		OLD	See endnote ⁵²
850.4150	Tier 2: Vegetative Vigor	44996101		OLD	See endnote ⁵³
850.4400, 850.5400	Tier 2: Aquatic Plant Growth	41888101 45161318 45161319 45161321 45161323 45161324 45161325 45161326 45161327		OLD OLD OLD OLD OLD OLD OLD OLD OLD GAP	See endnote ⁵⁴

Signature



Name and Title

Ann M. Tillman, Agent

Date

Jan. 3, 2017

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Applicant's/Registrant's Name & Address AXSS Technical Holdings, LLC 111 Martin Road Fulton, MS 38843		Product Imazethapyr Tech

Ingredient Imazethapyr (CAS No. 81335-77-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4300	Terrestrial Field				Not required
850.4450	Aquatic Field				Not required
850.4025	Target Area Phytotoxicity				Not required
850.4550	Aquatic Plant Growth (Cyanobacteria Toxicity)	45161320			
835.2120	Hydrolysis	00159752 00159753		OLD OLD	See endnote ⁵⁵
835.2240	Photodegradation in Water	40429407		OLD	See endnote ⁵⁶
835.2410	Photodegradation in Soil	40429408		OLD	See endnote ⁵⁷
835.2370	Photodegradation in Air				Not required
835.4100	Aerobic Soil Metabolism	40074201 40522601 45161328		OLD OLD OLD	See endnote ⁵⁸
835.4200	Anaerobic Soil Metabolism	40429409		OLD	See endnote ⁵⁹
835.4300	Aerobic Aquatic Metabolism	45161330		OLD	See endnote ⁶⁰
835.4400	Anaerobic Aquatic Metabolism	45161329		OLD	See endnote ⁶¹
835.1230; 835.1240	Leaching/Adsorption/Desorption	00159755 45161331		OLD OLD	See endnote ⁶²
835.1410	Volatility – Laboratory				Not required
835.8100	Volatility – Field				Not required

Signature 	Name and Title Ann M. Tillman, Agent	Date Jan. 3, 2017
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DATA MATRIX

Date Jan. 3, 2017	EPA Reg No./File Symbol 87427-RO	Page 11 of 18
Applicant's/Registrant's Name & Address AXSS Technical Holdings, LLC 111 Martin Road Fulton, MS 38843	Product Imazethapyr Tech	

Ingredient Imazethapyr (CAS No. 81335-77-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.6100	Soil Field Dissipation Study	40429410 40490101 41467701		OLD OLD OLD	See endnote ⁶³
835.6200	Aquatic Sediment Field Dissipation Study	45161332 45161333 45161341		OLD OLD OLD	See endnote ⁶⁴
835.6300	Forest Field Dissipation Study				Not required
835.6400	Combination and Tank Mixes				Not required
835.7100	Ground Water Monitoring	46123701 46123702	BASF Corporation BASF Corporation	PAY PAY	See endnote ⁶⁵
850.6100	Environmental Chemistry Methods	44865103 45161338 44746701 45161337		OLD OLD OLD OLD	See endnote ⁶⁶
860.1300	Nature of the Residue: Plants	40429405 41467702 41503502 41503503 41971901 45161341		OLD OLD OLD OLD OLD OLD	

Signature 	Name and Title Ann M. Tillman, Agent	Date Jan. 3, 2017
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Date Jan. 3, 2017

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Applicant's/Registrant's Name & Address

AXSS Technical Holdings, LLC
111 Martin Road
Fulton, MS 38843

Product

Imazethapyr Tech

Ingredient Imazethapyr (CAS No. 81335- 77-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1300	Nature of the Residue: Livestock	41503504 41503505 42658401 42658402		OLD OLD OLD OLD	
860.1850	Confined Rotational Crops	40429412		OLD	
860.1340	Residue Analytical Methods	41467705 41503501 41503507 41561502 41971903 42107201 43011701 43011702 43486801 44414601 45161334 45161335 45161336 46254703 46254704	BASF Corporation BASF Corporation	OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD PAY PAY	
860.1360	Multiresidue Method	40633701 41503508		OLD OLD	

Signature

Ann M. Fuller

Name and Title

Ann M. Tillman, Agent

Date

Jan. 3, 2017

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DATA MATRIX

Date Jan. 3, 2017	EPA Reg No./File Symbol 87427-RO	Page 13 of 18
Applicant's/Registrant's Name & Address AXSS Technical Holdings, LLC 111 Martin Road Fulton, MS 38843	Product Imazethapyr Tech	

Ingredient Imazethapyr (CAS No. 81335- 77-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1380	Storage Stability	41828101 41925901 42107202 42107203 42658404 44056302 45161337 45161339 45528001	BASF Corporation	OLD OLD OLD OLD OLD OLD OLD OLD PAY	
860.1500	Magnitude of the Residue in Plants: alfalfa	41971902 42658403		OLD OLD	
860.1500	Magnitude of the Residue in Plants: clover	44056301		OLD	
860.1500	Magnitude of the Residue in Plants: corn	42107204 42114401 42155201		OLD OLD OLD	
860.1500	Magnitude of the Residue in Plants: lettuce and endive	42869401		OLD	
860.1500	Magnitude of the Residue in Plants: legume vegetables (Group 6)	40997201		OLD	
860.1500	Magnitude of the Residue in Plants: peanuts	41467704		OLD	
860.1500	Magnitude of the Residue in Plants: rice	45161340		OLD	

Signature 	Name and Title Ann M. Tillman, Agent	Date Jan. 3, 2017
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DATA MATRIX

Date Jan. 3, 2017	EPA Reg No./File Symbol 87427-RO	Page 14 of 18
Applicant's/Registrant's Name & Address AXSS Technical Holdings, LLC 111 Martin Road Fulton, MS 38843		Product Imazethapyr Tech

Ingredient Imazethapyr (CAS No. 81335-77-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Magnitude of the Residue in Plants: soybeans	40429406 41164601 41561501 41598801		OLD OLD OLD OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: corn	42107205		OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: peanuts	41467704		OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: rice	45161340		OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: soybeans	40429406 41164601 41561501 41598801		OLD OLD OLD OLD	
860.1480	Magnitude of the Residue in Meat, Milk, Poultry, and Eggs	46254702	BASF Corporation	PAY	
860.1400	Nature and Magnitude of the Residue in Potable Water				Not required
860.1400	Magnitude of the Residue in Fish	45607101 46254701	BASF Corporation BASF Corporation	PAY PAY	
860.1400	Magnitude of the Residue in Plants Resulting from the Use of Irrigation Water				Not required

Signature 	Name and Title Ann M. Tillman, Agent	Date Jan. 3, 2017
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DATA MATRIX

Date Jan. 3, 2017		EPA Reg No./File Symbol 87427-RO		Page 15 of 18	
Applicant's/Registrant's Name & Address		Product			
AXSS Technical Holdings, LLC 111 Martin Road Fulton, MS 38843		Imazethapyr Tech			
Ingredient Imazethapyr (CAS No. 81335-77-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1460	Magnitude of the Residue in Food Handling Establishments				Not required
860.1900	Field Rotational Crops				Not required

Signature	Name and Title	Date
	Ann M. Tillman, Agent	Jan. 3, 2017

Endnotes for Imazethapyr Tech Data Matrix

- ¹ **830.1650** – Per OPPTS 830.1000, these data are not required for the registration of a technical product. See 830.1620 for production information.
- ² **830.6315 – Flammability:** AXSS Technical Holdings, LLC requests a waiver from this data requirement because Imazethapyr Tech is a solid and is not expected to be flammable. Please refer to the Confidential Statement of Formula for Imazethapyr Tech.
- ³ **830.6316 – Explodability:** AXSS Technical Holdings, LLC requests a waiver from this data requirement because Imazethapyr does not have the chemical bonds or functional groups associated with explosive chemicals.
- ⁴ **830.6319 – Miscibility:** This data requirement is required when the MUP is an emulsifiable liquid and to be diluted with petroleum solvents. Imazethapyr Tech is a solid and not an emulsifiable liquid to be diluted with petroleum solvents. This data requirement is not applicable to Imazethapyr Tech.
- ⁵ **830.6321 – Dielectric Breakdown Voltage:** These data are not required unless the product is an end-use product. This data requirement is not applicable to Imazethapyr Tech.
- ⁶ **830.7100 – Viscosity:** These data are required when the TGAI is a liquid. Imazethapyr Tech is a solid, and therefore this test is not applicable to Imazethapyr Tech.
- ⁷ **830.7220 – Boiling Point:** These data are required when the TGAI is a liquid. Imazethapyr Tech is a solid, and therefore this test is not applicable to Imazethapyr Tech.
- ⁸ **830.7520 – Particle size, fiber length, diameter distribution:** AXSS Technical Holdings, LLC is seeking a waiver for this data requirement for Imazethapyr Tech because it is not a fibrous material nor is a water insoluble material.
- ⁹ **870.1100:** The study cited is acceptable and satisfies the data requirement as per the March 12, 2014 Imazethapyr Human Health Assessment Scoping Document in Support of Registration Review (DP Barcode D415244) (Scoping Document).
- ¹⁰ **870.1200:** The study cited is acceptable and satisfies the data requirement as per the Scoping Document.
- ¹¹ **870.1300:** The study cited is acceptable and satisfies the data requirement as per the Scoping Document.
- ¹² **870.2400:** The study cited is acceptable and satisfies the data requirement as per the Scoping Document.
- ¹³ **870.2500:** The study cited is acceptable and satisfies the data requirement as per the Scoping Document.
- ¹⁴ **870.2600:** The study cited is acceptable and satisfies the data requirement as per the Scoping Document.
- ¹⁵ **850.2100:** The studies cited are acceptable and satisfy the data requirement as per the March 19, 2014 Registration Review Problem Formulation for Imazethapyr and Imazethapyr Ammonium Salt (DP Barcode D415245) (Problem Formulation). Note: the Problem Formulation states that passerine data are not required.
- ¹⁶ **850.2200:** The studies cited are acceptable and satisfy the data requirement as per the Problem Formulation.
- ¹⁷ **850.2300:** The studies cited are acceptable and satisfy the data requirement as per the Problem Formulation.
- ¹⁸ **850.1075:** The studies cited are acceptable and satisfy the data requirement as per the Problem Formulation. Note: the Problem Formulation also listed MRID 45161312, but this is an acute oyster toxicity study, not a freshwater fish study and is not cited here, but is cited under 850.1025, 850.1035, 850.1045, 850.1055, and 850.1075.
- ¹⁹ **850.1010:** The studies cited are acceptable or supplemental and satisfy the data requirement as per the Problem Formulation.
- ²⁰ **850.1025, 850.1035, 850.1045, 850.1055, 850.1075:** The studies cited are acceptable or supplemental and satisfy the data requirement as per the Problem Formulation.
- ²¹ **850.1300:** The study cited is acceptable and satisfies the data requirement as per the Problem Formulation.
- ²² **850.1350:** These data are not required as per the Problem Formulation.
- ²³ **850.1400:** The study cited is acceptable and satisfies the data requirement as per the Problem Formulation.
- ²⁴ **850.1400:** These data are not required as per the Problem Formulation.

Endnotes for Imazethapyr Tech Data Matrix

- ²⁵ **850.1710, 850.1730, 850.1850:** The study cited is supplemental, but satisfies the data requirement as per the Problem Formulation.
- ²⁶ **850.1735:** These data are not required as per the Problem Formulation.
- ²⁷ **850.1740:** These data are not required as per the Problem Formulation.
- ²⁸ **850.3020:** The study cited is under review as per the Problem Formulation.
- ²⁹ **N/A:** According to the Problem Formulation, this data requirement is reserved pending the review of the data under 850.3020.
- ³⁰ **N/A:** According to the Problem Formulation, this data requirement is reserved pending the review of the data under 850.3020.
- ³¹ **N/A:** According to the Problem Formulation, this data requirement is reserved pending the review of the data under 850.3020.
- ³² **850.3030:** These data are waived as per the August 5, 2013 Response to Public Comments on the Imazethapyr and Imazethapyr Ammonium Salt Registration Review Problem Formulation (DP Barcode D421435) (EFED Response to Comments).
- ³³ **870.6200:** These data are not required as per the Scoping Document.
- ³⁴ **870.3100:** The study cited is acceptable and satisfies the data requirement as per the Scoping Document.
- ³⁵ **870.3150:** The study cited is acceptable and satisfies the data requirement as per the Scoping Document.
- ³⁶ **870.3200:** The study cited is acceptable and satisfies the data requirement as per the Scoping Document.
- ³⁷ **870.3465:** These data are not required as per the Scoping Document.
- ³⁸ **870.6200:** These data are not required as per the Scoping Document.
- ³⁹ **870.4100:** The study cited is acceptable and satisfies the data requirement as per the Scoping Document.
- ⁴⁰ **870.4200:** The studies cited are acceptable and satisfy the data requirement as per the Scoping Document.
- ⁴¹ **870.3700:** The studies cited are acceptable and satisfy the data requirement as per the Scoping Document.
- ⁴² **870.3800:** The study cited is acceptable and satisfies the data requirement as per the Scoping Document.
- ⁴³ **870.5100:** The study cited is acceptable and satisfies the data requirement as per the Scoping Document.
- ⁴⁴ **870.5300, 830.5375:** The studies cited are acceptable and satisfy the data requirement as per the Scoping Document.
- ⁴⁵ **870.5385, 870.5395, 870.5450, 870.5550:** The studies cited satisfy the data requirement as per the Scoping Document.
- ⁴⁶ **870.7485:** The studies cited are acceptable and satisfy the data requirement as per the Scoping Document.
- ⁴⁷ **870.7800:** These data are not required as per the Scoping Document.
- ⁴⁸ **875.1100, 875.1300, 875.1500, 875.1600, 875.1700:** Tacoma Ag is an affiliate member of the Agricultural Handlers Exposure Task Force (AHETF). A letter of authorization for reliance on AHETF data can be provided upon request.
- ⁴⁹ **875.2100:** These data are not required as per the Scoping Document.
- ⁵⁰ **875.2200, 875.2400, 875.2500, 875.2600, 875.2700, 875.2800, 875.2900:** Tacoma Ag is an affiliate member of the Agricultural Re-Entry Task Force (ARTF) and the Outdoor Residential Exposure TF (ORETF). A letter of authorization for reliance on ARTF or ORETF data can be provided upon request.
- ⁵¹ **201-1, 202-1:** Tacoma Ag is an affiliate member of the Spray Drift Task Force (SDTF). A letter of authorization for reliance on SDTF data can be provided upon request.
- ⁵² **850.4100:** The study cited is under review as per the Problem Formulation.
- ⁵³ **850.4150:** The study cited is under review as per the Problem Formulation.

Endnotes for Imazethapyr Tech Data Matrix

- ⁵⁴ **850.4400, 850.5400:** The studies cited are acceptable or supplemental and satisfy the data requirement as per the Problem Formulation with the exception of CL266858 degradate, which is considered a data gap).
- ⁵⁵ **835.2120:** The studies cited are supplemental and acceptable, respectively, and satisfy the data requirement as per the Problem Formulation.
- ⁵⁶ **835.2240:** The study cited is supplemental but satisfies the data requirement as per the Problem Formulation.
- ⁵⁷ **835.2410:** The study cited is supplemental but satisfies the data requirement as per the Problem Formulation.
- ⁵⁸ **835.4100:** The studies cited are acceptable (or supplemental) and satisfy the data requirement as per the Problem Formulation.
- ⁵⁹ **835.4200:** The study cited is acceptable and satisfies the data requirement as per the Problem Formulation.
- ⁶⁰ **835.4300:** The study cited is supplemental but satisfies the data requirement as per the Problem Formulation.
- ⁶¹ **835.4400:** The study cited is acceptable and satisfies the data requirement as per the Problem Formulation.
- ⁶² **835.1230, 835.1240:** The studies cited are acceptable and satisfy the data requirement as per the Problem Formulation.
- ⁶³ **835.6100:** *The studies cited are acceptable (or supplemental) and satisfy the data requirement as per the Problem Formulation.*
- ⁶⁴ **835.6200:** The studies cited are supplemental, but satisfy the data requirement as per the Problem Formulation.
- ⁶⁵ **835.7100:** MRID 46123702 is listed in the Problem Formulation and no additional data are required. However, at the request of EPA, MRID 46123701 is also cited.
- ⁶⁶ **850.6100:** The studies cited are supplemental, but satisfy the data requirement as per the Problem Formulation.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

FEE

87427-RO

BAR CODE No.: D432436 FILE SYMBOL No.: ~~83520-60~~ DECISION No.: 514742:
PRODUCT NAME: ~~Tacoma AG~~ Imazethapyr Technical PC Code(s): 128922: ACTION CODE:
R334; FOOD Use: No

This Document Contains Confidential Information

DATE OUT: 12/13/16

SUBJECT: Product Chemistry Review of TGAI
Product Name: Tacoma AG Imazethapyr Technical

FROM: Indira Gairola / Product Chemistry Team
CITAB/RD (7505P)

TO: Lisa Pahel / Heather Garvie RM 24
FH Branch / Registration Division (7505P)

COMPANY: Tacoma AG, LLC
Active Ingredient(s): Imazethapyr Technical (98.4%)

MRID No(s). 498415-01 to -04

INTRODUCTION:

Registrant is submitting registration application for subject product Tacoma AG Imazethapyr Technical Basic Formulation CSF dated 03/03/16 (MRID# 498415-01 to -04) produced by [REDACTED] for product chemistry Group A and Group B data to support this application.

CITAB (Chemistry Team) has been asked to determine the acceptability of the aforementioned subject product chemistry data and CSF.

SUMMARY OF FINDINGS:

1. Group A guidelines: 830.1550 (Product identity & composition) MRID #498415-01. Data for the identity and position of the product were provided. The active ingredient "Imazethapyr Technical" is present at a nominal concentration of Basic Formulation 98.4%. The product chemistry data submitted corresponding to Guideline 830.1550 satisfy the data requirements of 40CFR§158.320.

BAR CODE No.: D432436 **FILE SYMBOL No:** 83520-GO: **DECISION No.:** 514742;
PRODUCT NAME: Tacoma AG Imazethapyr Technical **PC Code(s):** 128922: **ACTION CODE:** R334; **FOOD Use:** No

830.1600 (Description of materials used to produce the product) MRID #s 498415-01. The registrant provided a list of suppliers and MSDSs for the materials used to produce the product. The product chemistry data submitted corresponding to Guideline 830.1600 satisfy the data requirements of 40CFR§158.325.

830.1620 (Description of production process) 498415-01 The production process by was described by [REDACTED] The product chemistry data submitted corresponding to Guideline 830.1620 satisfy the data requirements of 40CFR§ 158.330

830.1670 (Discussion on the formation of impurities). 498415-01. A discussion of the origin and mechanism formation for the impurities in the product was provided. Applicant provided analyses of all process related impurities. The Analysis was performed using validated methods of technical by HPLC/MS equipped with UV detector. External standard quantitation methods were used to quantify the levels of a.i. and associated impurities only one impurity was detected of no significant toxicological concern as per CITAB. Data submitted corresponding to Guideline 830.1670 satisfy the data requirements of 40CFR§158.340.

830.1700 (Preliminary analysis) #498415-03. Results of a five-batch preliminary analysis were provided in. The total recovery content of a.i are within the certified limits specified on the CSF dated 03/03/16. The product chemistry data submitted corresponding to Guideline 830.1700 satisfy the data requirements of 40CFR§158.345.

30.1750 (Certified limits) for Basic CSF dated 03/03/16. Certified limits were provided for the active ingredient and upper certified limits were provided for the impurities in the product. Content of a.i. ranged from 95.4% -100% with an average of 98.%. The proposed upper limit is 100 % and the lower limit is 95.4%.

The product chemistry data submitted corresponding to Guideline 830.1750 satisfy the data requirements of 40CFR§158.350

830.1800 (Enforcement analytical method) MRID #498415-02. A description of the enforcement analytical method and its validation were provided. The Analysis of technical by HPLC- equipped with UV detectors & MS spectrometry were used. TGA1 was validated for specificity, linearity, accuracy, precision. Average total closure of the five lots samples was reported. The product chemistry data submitted corresponding to Guideline 830.1800 satisfy the data requirements of 40CFR§158.355.

For details please refer to the Confidential Appendix

2. Group B guidelines (physical-chemical properties) The Data submitted is listed in the following pages.

BAR CODE No.: D432436 **FILE SYMBOL No:** 83520-GO: **DECISION No.:** 514742;
PRODUCT NAME: Tacoma AG Imazethapyr Technical **PC Code(s):** 128922: **ACTION CODE:**
R334; **FOOD Use:** No

CONCLUSIONS:

The (CITAB/ Product Chemistry Team has reviewed the product chemistry data submitted for “Imazethapyr Technical” and concluded:

1. All product chemistry data submitted for guideline 830 Series group A are acceptable.
2. The Basic CSF dated 03/03/16 is determined acceptable.
3. No impurity of significant toxicological concern was identified as per CITAB, for details please refer to the Confidential Appendix and summary of findings.
4. Product chemistry data corresponding to 830 series group B (Physical-Chemical properties) are listed in the following pages. All data have been determined acceptable.

BAR CODE No.: D432436 FILE SYMBOL No: 83520-GO: DECISION No.:514742;
PRODUCT NAME: Tacoma AG Imazethapyr Technical PC Code(s):128922: ACTION CODE:
R334; FOOD Use: No

Table 1 Summary of Test Results Imazethapyr TGA1

Test	Test Conditions	Result
Color	15.0 °C	Off-white
Physical State	15.0 °C	Powder
Odor	15.0 °C	Odorless
Stability	Room Temperature (Accelerated Storage Stability)	The Test Item is stable for 14 Days at Room Temperature
	54 ± 2 °C (Accelerated Storage Stability)	The Test Item is stable for 14 Days at 54 ± 2 °C.
	Room Temperature (Stability to Metals and Metal Ions)	The Test Item is considered to be stable in terms of Active Ingredient content when exposed to iron, aluminium, copper, iron acetate, aluminium acetate and copper acetate for 14 Days at room temperature (15 ~ 17°C).
	54 ± 2 °C (Stability to Metals and Metal Ions)	The Test Item is considered to be stable in terms of Active Ingredient content when exposed to iron, aluminium, copper, iron acetate, aluminium acetate and copper acetate for 14 Days at 54 ± 2 °C.
Corrosion Characteristics	Room Temperature	No corrosion of the commercial packages after storage for 14 days at Room Temperature.
	54 ± 2 °C	No corrosion of the commercial packages after storage for 14 days at 54 ± 2 °C.
Oxidation/Reduction	Room Temperature	The Test Item is considered to be non-reactive with water, n-hexane, NH ₄ H ₂ PO ₄ and iron powder.
pH (1% w/v)	Room Temperature	3.19
UV/Visible Absorption	pH=5.62	2.60×10^{-4} (L/mol·cm) at 193.81 nm
	pH=1.84	2.51×10^{-4} (L/mol·cm) at 198.38 nm
	pH=11.40	2.28×10^{-4} (L/mol·cm) at 200.15 nm

BAR CODE No.: D432436 FILE SYMBOL No: 83520-GO: DECISION No.:514742;
PRODUCT NAME: Tacoma AG Imazethapyr Technical PC Code(s):128922: ACTION CODE:
R334; FOOD Use: No

Melting Point	-	176.7 °C ~ 177.2 °C
Density	20.0 ± 0.5 °C	1.2431 g/cm ³
Dissociation Constant	Room Temperature	1.94
Partition Coefficient (n-Octanol/Water)	25.0 ± 0.5 °C	LogP _{ow} = 1.52
Solubility	20.0 ± 0.5 °C	Water (pH = 6.64) 1.30 g/L
		Acetone 28.20 g/L
		Ethyl Acetate 15.61 g/L

Room Temperature was recorded at the day of experiments, and presented in Section 4.

BAR CODE No.: D432436 FILE SYMBOL No: 83520-GO: DECISION No.:514742;
PRODUCT NAME: Tacoma AG Imazethapyr Technical **PC Code(s):128922: ACTION CODE:**
R334; FOOD Use: No

Tacoma Ag Imazethapyr Tech contains 98.4% of imazethapyr. The CAS nomenclature is (\pm) -2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl-3-pyridinecarboxylic acid. The Chemical Abstracts number is 81335-77-5. The Chemical Code is 128922. Tacoma Ag, LLC is requesting waivers or citing public literature data for certain for physical and chemical property data requirements as described in the table below.

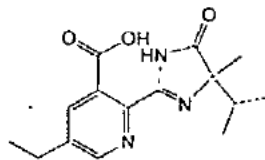
Guideline No.	Title	Discussion
830.6315	Flammability	Tacoma Ag, LLC requests a waiver from this data requirement because Tacoma Ag Imazethapyr Tech is a solid, does not contain flammable components, and therefore is not expected to be flammable.
830.6316	Explosibility	Tacoma Ag, LLC requests a waiver from this data requirement because Imazethapyr does not have the chemical bonds or functional groups associated with explosive chemicals.
830.6319	Miscibility	This data requirement is required when the MUP is an emulsifiable liquid and to be diluted with petroleum solvents. Tacoma Ag Imazethapyr Tech is a solid and not an emulsifiable liquid to be diluted with petroleum solvents. This data requirement is not applicable to Tacoma Ag Imazethapyr Tech.
830.7100	Viscosity	These data are required when the TGA1 is a liquid. Tacoma Ag Imazethapyr Tech is a solid, and therefore this test is not applicable to Tacoma Ag Imazethapyr Tech.
830.7220	Boiling Point	These data are required when the TGA1 is a liquid. Tacoma Ag Imazethapyr Tech is a solid, and therefore this test is not applicable to Tacoma Ag Imazethapyr Tech.
830.7520	Particle size, fiber length, and diameter distribution	Tacoma Ag, LLC is seeking a waiver for this data requirement for Imazethapyr because it is not a fibrous material or a water-insoluble material.
830.7950	Vapor Pressure	Tacoma Ag, LLC is citing public literature data for the vapor pressure of Imazethapyr. The vapor pressure is 1.3×10^{-2} mPa (25°C). (Reference: Tomlin, C. D. S. (Ed.). "The Pesticide Manual", 13 th Edition, p. 559. BCPC Publications, Hampshire, 2003).

BAR CODE No.: D432436 **FILE SYMBOL No:** 83520-GO: **DECISION No.:** 514742;
PRODUCT NAME: Tacoma AG Imazethapyr Technical **PC Code(s):** 128922: **ACTION CODE:**
R334; **FOOD Use:** No

IDENTITY

Tacoma Ag Imazethapyr Tech contains 98.4% of imazethapyr. The CAS nomenclature is (\pm) -2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl-3-pyridinecarboxylic acid. The IUPAC name is (RS)-5-ethyl-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)nicotinic acid. The Chemical Abstracts number is 81335-77-5. The Chemical Code is 128922. Tacoma Ag Imazethapyr Tech is substantially similar to Pursuit Herbicide Technical, EPA Reg. No. 241-309.

The molecular formula for imazethapyr is $C_{15}H_{19}N_3O_3$ and the molecular weight is 289.3. Its structure is shown below:



Imazethapyr

Imazethapyr is a branched chain amino acid synthesis (ALS or AHAS) inhibitor. Formation of valine, leucine and isoleucine in the plant is reduced and leads to disruption of protein and DNA synthesis. It is a systemic herbicide that is absorbed by roots and foliage and translocated in the xylem and phloem. Imazethapyr controls many major annual and perennial grass and broad-leaved weeds in a number of crops and not crop sites.

The detailed composition of Tacoma Ag Imazethapyr Tech is presented on a Confidential Statement of Formula, EPA Form 8570-4, which has been removed to the Confidential Attachment at Cross Reference Number 1.

MATERIALS TO PRODUCE THE PRODUCT ARE LISTED IN THE FOLLOWING



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D432436 FILE SYMBOL No.: 83520-GO (screen) DECISION No.: 514742
PC Code: 128922 Company Name: Tacoma AG, LLC
FOOD Use: No ACTION CODE: R 334 PRODUCT NAME: Tacoma Ag Imazethapyr Tech

DATE OUT: April 13, 2016

SUBJECT: Completeness Check Screen for Manufacturing Use Product

Product Name: Tacoma Ag Imazethapyr Tech

FROM: Bruce Kitchens, Chemist
Product Chemistry Team
Chemistry, Inerts and Toxicology Assessment Branch/RD (7505P)

Bruce Kitchens
4/13/16

TO: RM# 24, Heather Garvie/Lisa Pahel
Fungicide and Herbicide Branch / RD (7505P)

Company Name: Tacoma AG, LLC
Active Ingredient: Imazethapyr (98.4% ai)

MRID Nos.: 498415-01 thru 498415-04

CONCLUSION:

Deficiencies: None
(If there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

Group A: All required data submitted

Group B: All data required submitted.

CSF: Basic CSF dated 03 Mar 2016 submitted.

Product label: Yes

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and return to me or to Joe the corrected deficiencies in response to 10 day letter, so that it can be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D432436 FILE SYMBOL No.: ⁸⁷⁴²⁷⁻²⁰~~83526-00~~ (screen) DECISION No.: 514742
PC Code: 128922 Company Name: Tacoma AG, LLC
FOOD Use: No ACTION CODE: R 334 PRODUCT NAME: Tacoma Ag Imazethapyr Tech

DATE OUT: April 13, 2016

SUBJECT: Completeness Check Screen for Manufacturing Use Product

Product Name: Tacoma Ag Imazethapyr Tech

FROM: Bruce Kitchens, Chemist
Product Chemistry Team
Chemistry, Inerts and Toxicology Assessment Branch/RD (7505P)

Bruce Kitchens
4/13/16

TO: RM# 24, Heather Garvie/Lisa Pahel
Fungicide and Herbicide Branch / RD (7505P)

Company Name: Tacoma AG, LLC
Active Ingredient: Imazethapyr (98.4% ai)

MRID Nos.: 498415-01 thru 498415-04

CONCLUSION:

Deficiencies: None
(If there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

Group A: All required data submitted

Group B: All data required submitted.

CSF: Basic CSF dated 03 Mar 2016 submitted.

Product label: Yes

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and return to me or to Joe the corrected deficiencies in response to 10 day letter, so that it can be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION

15/MAR/2016

SIMILARITY CLINIC MEMORANDUM

Subject: Name of Pesticide Product: Tacoma Ag Imazethapyr Tech
EPA Reg. No. /File Symbol: ~~83520-GO~~ 87427-PO
DP Barcode: D432245
Decision No: 514742
Action Code: R334
PC Code: 128922 (imazethapyr)

From: Eugenia McAndrew, Biologist *Eugenia McAndrew*

Through: John C. Redden, M.S., Senior Risk Assessor *JCR*
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)

To: Venus Eagle, Risk Manager Team 01
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)

Applicant: Tacoma Ag, LLC
P.O. Box 14073
Durham, NC 27709

FORMULATION FROM LABEL:

Active Ingredient(s):	<u>% by wt.</u>
Imazethapyr	98.4
Other ingredients:	<u>1.6</u>
Total:	100.0

ACTION REQUESTED: Similarity determination for 83520-GO, proposed product, and 241-309, cited product.

BACKGROUND: Tacoma Ag, LLC has applied for registration of Tacoma Ag Imazethapyr Tech, EPA File Symbol 83520-GO, claiming to be substantially similar to Pursuit Herbicide Technical, EPA Reg. No. 241-309. Both products are technical grade for manufacturing use only. The submission includes a basic CSF dated March 3, 2016, label, data matrix and company letter.

The registrant is using the selective method of data support to satisfy the acute toxicity data requirements. The data matrix cites the following acute toxicity studies: acute oral (MRID 00159375), acute dermal (MRID 00159375), acute inhalation (MRID 00159378), primary eye irritation (MRID 00159375), primary dermal irritation (MRID 00159375) and dermal sensitization (MRID 00159379). A search of the OPP electronic databases shows that the Health Effects Division reviewed the available toxicological database for imazethapyr in a 2002 memo including these cited studies (Shah; D240998; TXR No. 0050339; 06/MAR/2002).

RECOMMENDATIONS:

1. We compared the basic CSFs and labels of the proposed product, 83520-GO, and the cited product, 241-309, and determined that the two products are substantially similar. The cited acute toxicity data may be used to support this registration.
2. The acute toxicity profile for the proposed product, Tacoma Ag Imazethapyr Tech, EPA File Symbol 83520-GO, is as follows:

acute oral toxicity	IV	cited	MRID 00159375
acute dermal toxicity	III	cited	MRID 00159375
acute inhalation toxicity	IV*	cited	MRID 00159378
primary eye irritation	III	cited	MRID 00159375
primary skin irritation	IV	cited	MRID 00159375
dermal sensitization	negative	cited	MRID 00159379

*Originally placed in Toxicity Category III but by today's standards it is in Toxicity Category IV.

3. The proposed basic CSF submitted for 83520-GO must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 083520-00039

PRODUCT NAME: Tacoma Ag Imazethapyr Tech

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Wear protective eyewear, if appropriate.

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 03, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MS. NICOLE O'LOUGHLIN
PYXIS REGULATORY CONSULTING INC, AGENT FOR
AXSS TECHNICAL HOLDINGS, LLC
4110 136TH ST CT NW
GIG HARBOR, WA 98332

Dear Ms. O'Loughlin:

Subject: Transfer of Pesticide Registrations and Data From Company Number **83520**
to Company Number **87427**

Pursuant to your request in your letter and transfer agreement received July 05, 2016,
we have approved the transfer of the following registrations from **TACOMA AG, LLC**,
company number **83520** to **AXSS TECHNICAL HOLDINGS, LLC**, company number **87427**.

The effective date of these changes is the date of this letter.

<u>Registered Products</u>	<u>Old EPA Reg. No.</u>	<u>New EPA Reg. No.</u>
MEPIQUAT CHLORIDE TECHNICAL	83520-1	87427-2
BIFENTHRIN TECHNICAL	83520-5	87427-4
GLYPHOSATE 62% MANUFACTURING CONCENTRATE	83520-6	87427-5
DICAMBA ACID TECHNICAL	83520-8	87427-6
2,4-D ACID TECHNICAL	83520-9	87427-7
2,4-D AMINE MANUFACTURING CONCENTRATE	83520-15	87427-8
2,4-D ESTER MANUFACTURING CONCENTRATE	83520-16	87427-9
GLYPHOSATE ACID TECHNICAL	83520-17	87427-10

CLETHODIM 37% MUP	83520-23	87427-11
SODIUM ACIFLUORFEN 44% MUP	83520-25	87427-12
SODIUM BENTAZON 55.9% MUP	83520-27	87427-13
TEBUCONAZOLE TECHNICAL	83520-30	87427-14
THIOPHANATE-METHYL TECHNICAL	83520-31	87427-15
ETHEPHON MUP	83520-34	87427-16

<u>Pending Registered Products</u>	<u>Old EPA File Symbol</u>	<u>New EPA File Symbol</u>
Tacoma Ag Imidacloprid Tech	83520-GA	87427-G
Tacoma Ag Fomesafen Tech	83520-GT	87427-RT
Tacoma Ag Diflubenzuron Tech	83520-GI	87427-RI
Tacoma Ag Imazethapyr Tech	83520-GO	87427-RO

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or

labeling may require EPA review and approval prior to distribution or sale of the product containing the new registration number. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

With regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

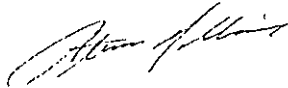
Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The annual maintenance fee is based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer received July 05, 2016 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date **AXSS TECHNICAL HOLDINGS, LLC** will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Louis Vaughn at (703) 308-8114.

Sincerely,



Steve Robbins, Chief
Information Services Branch
Information Technology & Resource Management Div. (7504P)

cc: MS. ANN TILLMAN
PYXIS REGULATORY CONSULTING, INC., AGENT FOR
TACOMA AG, LLC
4110 136TH ST, CT NW
GIG HARBOR, WA 98332

RE: L_83520_RAD_87427_10_03_2016

Waiting for date
AB 03/11/16

21-Day Screen Completed by
Contractor

21-Day Expires on 3/28/16

Jacket # 83520-GO

MRID# 498415

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

Steve Schaible

01

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 3-7-16

Experts In-Processing Signature: B.B. Date 3-9-16 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>83520-G0</u>		EPA Receipt Date: <u>3-7-16</u>			
Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type		X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)		X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	<div style="display: flex; justify-content: space-between;"> yes no </div> <div style="text-align: center; font-size: 1.2em; margin-top: 5px;">No inerts to review</div>			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)		X		
	Certificate and data matrix consistent		X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	<div style="display: flex; justify-content: space-between;"> yes no </div>			
	If applicable, is there a letter of Authorization for exclusive use only.				
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)				X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)		X		
5	a) Selective Method (Fee category experts use)	<div style="display: flex; justify-content: space-between;"> yes no </div> <div style="text-align: center;">X</div>			
	b) Cite-All (Fee category experts use)				
	c) Applicant owns all data (Fee category experts use)				
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)		X		
7	Is the data package consistent with PR Notice 86-5		X		
8	Notice of Filing included with petitions				X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

Documentation: PASS

- All required forms are complete.

Inerts: N/A

- Technical and impurities only. no inerts to review.

11-3: PASS

- MRID 498415

Status: PASS

- MS 03-10-16

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 8, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-514742
EPA File Symbol or Registration Number: 83520-GO
Product Name: Tacoma Ag Imazethapyr Tech
EPA Receipt Date: 07-Mar-2016
EPA Company Number: 83520
Company Name: TACOMA AG, LLC

ANN TILLMAN
PYSIS REGULATORY CONSULTING INC
TACOMA AG, LLC
4110 136TH ST, CT NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R334

NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF
THE ACTIVE INGREDIENT;REQUIRES SCIENCE DATA REVIEW;NEW PHYSICAL
FORM;SELECTIVE DATA CITATION;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely,

Teresa Downs
Front End Processing Staff

Information Technology & Resources Management Division

Fee for Service

1
{9824083~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr.

 24

Receipt No.

S-

982408

EPA File Symbol/Reg. No.

83520-GO

Pin-Punch Date:

3/7/2016

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R334

Granted:

R534

Amount Due: \$ 19,838

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐

Uncleared Inert in Product

Reviewer: 

Date: _____

Remarks:

DOCUMENTUM

Receipt for Section 3					
S: 982408	Milestone Email: Ann@PyxisRC.com				
Regulatory Type:	Product Registration - Section 3	Resubmission:	<input checked="" type="radio"/> Yes <input type="radio"/> No	<div>Print Letter</div> <div>Enter More Information</div> <div>Tracking</div>	
Application Type:	New Registration	Fee For Service:	<input checked="" type="radio"/> Yes <input type="radio"/> No		
Company:	83520 TACOMAAG, LLC	Billable:	<input checked="" type="radio"/> Yes <input type="radio"/> No		
Risk Manager:	Registration Division, Risk Management Team 1				
Product #:	83520-GO	Product Name: Tacoma Ag Imazethapyr Tech			
Override#:					
Me Too Section3:	241-309	Me Too Product Name:	PURSUIT HERBICIDE TECHNICAL		
Application Date:	07-Mar-2016	OPP Rec'd Date:	07-Mar-2016	<div>Receipt Content</div> <div>Study</div> <div>CSF</div> <div>View/Edit</div>	
Front End Date:	07-Mar-2016	Risk Manager Send Date:			
FFS Due Date:		Negotiated Due Date:			
OPP Target Date:					
Fast Track:	<input type="checkbox"/>	New Ingredient:	<input type="checkbox"/>		
<div>Receipt Description:</div> <div>Portal submission # 10367. Application for new registration.</div>					
Form A:	<input type="checkbox"/>	Signature Date:		Form B:	<input type="checkbox"/>

DOCUMENTUM

Ann Tillman

From: notification@pay.gov
Sent: March 07, 2016 8:26 AM
To: Ann Tillman
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25QBJK1T
Agency Tracking ID: 74972984290
Transaction Type: Sale
Transaction Date: 03/07/2016 08:25:46 AM EST

Account Holder Name: Jeanne Howard

Transaction Amount: \$19,838.00
Card Type: AmericanExpress
Card Number: *****1013

Registration Number:
Company Name: Tacoma Ag, LLC
Company Number: 83520
Action Code: R334

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

DOCUMENTUM

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. Ct. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

March 7, 2016

MRID 498415-00

ELECTRONIC DELIVERY

Heather Garvie (PM 24)
Document Processing Desk (**REGFEE**)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Tacoma Ag, LLC
Tacoma Ag Imazethapyr Tech (EPA File Symbol 83520-)
Application for New Pesticide Registration
PRIA Category R334

Dear Ms. Garvie,

On behalf of Tacoma Ag, LLC, we are submitting an application for registration of Tacoma Ag Imazethapyr Tech, a technical product containing the active ingredient imazethapyr. In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Certification with Respect to Citation of Data (EPA Form 8570-34)
4. Agency Internal Use Copy of the Data Matrix (EPA Form 8570-35)
5. Public File Copy of the Data Matrix (EPA Form 8570-35)
6. One (1) copy of the proposed label for Tacoma Ag Imazethapyr Tech
7. Copy of the PRIA payment
8. Letter of Authorization
9. Product Specific Data:

MRID	Guideline	Study Title
49841501	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Tacoma Ag Imazethapyr Tech. <i>Contains Confidential Business Information.</i>
49841502	830.1700, 830.1800	Xu, J. Five-Batch Analysis of Imazethapyr TGA1 – Validation of Analytical Methodology for the Assay of Active Ingredient and Impurities in Imazethapyr TGA1 and Subsequent 5-Batch Analysis of the Test Item. <i>Contains Confidential Business Information.</i>

DOCUMENTUM

MRID	Guideline	Study Title
49841503	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6317, 830.6320, 830.7000, 830.7050, 830.7200, 830.7300, 830.7370, 830.7550, 830.7840	Xu, J. Physical and Chemical Characterization of Imazethapyr TGA1-Color, Physical State, Odor, Stability, Corrosive Characteristic, Oxidation/Reduction, pH, UV/Vis Absorption, Density, Dissociation Constant, Melting Point, Partition Coefficient and Solubility.
49841504	830.6315, 830.6316, 830.6319, 830.7100, 830.7220, 830.7520, 830.7950	Tillman, A. M. Tacoma Ag Imazethapyr Tech Physical and Chemical Properties and Waiver Requests.

Tacoma Ag, LLC is using the selective method of data support. As per EPA's interpretations of 40 CFR Parts 152.90 - 152.96, Tacoma Ag, LLC submitted notices of intent to apply and offers to pay to the extent required by FIFRA § 3(c)(1)(F). This action falls under Category R334 (S4: New MUP with unregistered source of active ingredient; selective data citation). The fee due which has been paid is \$19,838.

We trust you will find this application complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone at (253) 853-7369 if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures

cc: K. Howard, Tacoma Ag, LLC

